



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Neurological Disorder and Stroke
FOIA/PA Office, RKL 1, Suite 6054
6705 Rockledge Drive
Bethesda, MD 20892

September 19, 2019

Austin Evers
American Oversight
1030 15th Street, B255
Washington, DC 20005

Re: FOIA Case Number: 51763

Dear Mr. Evers:

This is our final response to your Freedom of Information Act (FOIA) request addressed to National Institute of Neurological Disorder and Stroke (NINDS), National Institutes of Health (NIH), dated and received July 22, 2019. You requested all email communications beginning May 1, 2018, through the date of the search (including emails, email attachments, calendar invitations, and any attachments thereto) between or among 1) Linda L. Porter, Ph.D., Director, Office of Pain Policy, National Institute for Neurological Disorders and Stroke, National Institutes of Health, and any 2) employee or representative of the following drug and device manufacturers and their subsidiaries or affiliates:

- a. Purdue, including Purdue Pharma L.P.; Purdue Pharma, Inc.; and The Purdue Frederick Company, Inc. (@purduepharma.com)
- b. Allergan, including Allergan PLC; Allergan Finance, LLC; Allergan USA, Inc.; and Allergan Sales, LLC (@allergan.com)
- c. Teva, including Teva Pharmaceuticals Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc.; Actavis Laboratories FL, Inc.; and Andrx Corporation (@tevapharm.com)
- d. Johnson & Johnson, including Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; and Janssen Pharmaceutica, Inc. (@its.jnj.com; @jnj.com)
- e. Endo, including Endo Health Solutions Inc., Endo Pharmaceuticals, Inc.; Endo International plc; Par Pharmaceutical, Inc.; and Par Pharmaceuticals Companies, Inc. (@endo.com)
- f. Mallinckrodt, including Mallinckrodt plc; Mallinckrodt LLC; and SpecGx LLC (@mnk.com)
- g. Insys Therapeutics, Inc. (@insysrx.com)
- h. Noramco, Inc. (@noramco.com)
- i. Assertio Therapeutics, Inc. (f/k/a Depomed, Inc.) (@assertiotx.com; @depomed.com)
- j. Eli Lilly and Company (@lilly.com)
- k. Pfizer, including Pfizer Inc. and King Pharmaceuticals LLC (@pfizer.com)
- l. Iroko Pharmaceuticals, including Iroko Pharmaceuticals, LLC and Iroko Pharmaceuticals, Inc. (@iroko.com)
- m. Daiichi Sankyo, including Daiichi Sankyo, Inc. and American Regent (@dsi.com)
- n. Stimwave, including Stimwave Technologies, Inc. and Stimwave LLC (@stimwave.com)
- o. Braeburn Inc. (@braeburnrx.com)
- p. Medtronic plc (@medtronic.com)

Page 2: FOIA Case Number: 51763

We searched the files of NINDS for records responsive to your request. That search produced 36 pages responsive to your request. Enclosed are all email communications between or among (1) Linda L. Porter, Ph.D., Director, Office of Pain Policy, NINDS and (2) any employee or representative of several drug and device manufacturers and their subsidiaries or affiliates. It is Department of Health and Human Services (HHS) policy to expunge passcodes, personal information, and private sources of support wherever they appear throughout the material. This information has been removed from the enclosed material.

Please feel free to call me on 301-496-9737 for additional information or to inquire about your request.

If you are not satisfied with the processing and handling of this request, you may contact the NINDS FOIA Public Liaison:

NINDS FOIA Public Liaison

Marianne Manheim
Rockledge I, Suite 6054
6705 Rockledge Drive
Bethesda, MD 20892
301-496-9737 (phone)
301-402-3604 (fax)
marianne.manheim@nih.gov (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the \$25 minimum, there is no charge for the enclosed materials.

Sincerely,



Kathryn Gonzalez
Government Information Specialist, NINDS

Enclosures: 36 pages

Received.

@tevapharm.com and @its.jnj.com

From: Pelleymounter, Mary (NIH/NINDS) [E] <mary.pelleymounter@nih.gov>

Sent: Monday, September 17, 2018 11:33 AM

To: Martin S Angst <ang@stanford.edu>; Ernesto Ramirez <eramirez@evidation.com>; ncalcutt@ucsd.edu; Dr. JT Kong <jtkong@stanford.edu>; Sean Mackey <smackey@stanford.edu>; Davis, Karen <Karen.Davis@uhnresearch.ca>; Luda Diatchenko, Dr. <luda.diatchenko@mcgill.ca>; Dr. Klaus Klaus Schaf Schaffler MD (k.schaffler@hpr-cro.com) <k.schaffler@hpr-cro.com>; Irene Tracey <irene.tracey@ndcn.ox.ac.uk>; Iadarola, Michael (NIH/CC/SURG) [C] <michael.iadarola@nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Papadopoulos, Elektra (FDA/CDER) <elektra.papadopoulos@fda.hhs.gov>; Koroshetz, Walter (NIH/NINDS) [E] <koroshetzw@ninds.nih.gov>; Volkow, Nora (NIH/NIDA) [E] <nvolkow@nida.nih.gov>; Thomas, David (NIH/NIDA) [E] <dthomas1@nida.nih.gov>; Leptak, Christopher (FDA/CDER) <christopher.leptak@fda.hhs.gov>; Vargas, Gabriel <gavargas@amgen.com>; [REDACTED]; [REDACTED]; Martha Brumfield <MBrumfield@c-path.org>; Simon Tate <simon@bridgevalleyventures.com>; Lara Mangravite <lara.mangravite@sagebionetworks.org>; Green, Carmen (Carmen) <carmeng@med.umich.edu>; Don Berry <don@berryconsultants.net>; Joachim Scholz [REDACTED] Mark Mintun <mintun@avidrp.com>; Ibecerra@invicro.com; Wang, Jing (Anesthesiology) <Jing.Wang2@nyumc.org>; Wasan, Ajay <wasanad@upmc.edu>; Edwards, Robert Randolph, Ph.D. <rredwards@bwh.harvard.edu>; Hincapie, Juan <Juan.Hincapie@bsci.com>; NKatz@analgesicsolutions.com; carl_saab@brown.edu; William Maixner, D.D.S., Ph.D. <william.maixner@duke.edu>; Kolb, Hartmuth [JRDUS] <hkolb1@ITS.JNJ.com>; Tor Wager [REDACTED] Harris, Rick <reharris@med.umich.edu>; David Borsook <david.borsook@childrens.harvard.edu>; Fillingim, Roger Benton <RFillingim@dental.ufl.edu>; Freeman, Roy (HMFP - Neurology) <rffreeman@bidmc.harvard.edu>; Apkarian <apkarian@northwestern.edu>; Woolf, Clifford <Clifford.Woolf@childrens.harvard.edu>; Sang, Christine Nai-Mei, M.D., M.P.H. <CSANG@bwh.harvard.edu>; michael.burczynski@tevapharm.com; Simon Tate <simon@bridgevalleyventures.com>; Wendy M. Schadle <wendy3@stanford.edu>

Subject: Requested materials for HEAL Pain Biomarkers Workshop Needed by October 15

Dear Speakers for the NIH Workshop, "Discovery and Validation of Biomarkers to Develop Non-Addictive Therapeutics for Pain",

We are in the process of collecting presentation materials in preparation for the **Discovery and Validation of Biomarkers to Develop Non-Addictive Therapeutics for Pain** workshop. We are asking that you please submit a brief biography and your abstract (including the presentation title) to Ms. Terry Kerere at tkerere@betah.com as soon as possible but no later than October 15. Attached are sample templates to guide you through the preparation of your biography and abstract. Adopting these guidelines will assist us with the final production phase of handouts.

In the final week leading up to the workshop, Ms. Kerere will request that you email her your final presentation. Ms. Kerere will be responsible for coordinating onsite audiovisual support with the dedicated AV technician who will load presentations to the podium laptop and

conduct a test with you upon your arrival. We prefer that you present from the podium laptop (Microsoft PC) to help mitigate any potential technical challenges and delays that could result from transitioning between equipment. We also want to remind you that the workshop will be streamed live and the webcast will be archived for future views. Additional details about the workshop's format (e.g., introductions, seating arrangements, available audiovisual equipment) will be forthcoming.

Session Chairs: If you have not done so yet, please begin to work with the speakers from your session to finalize presentation titles and to assure coordination of talk content. Contact information is in the email list above, but if you need any other information to get the process started, please let me know. I have attached the most recent version of the agenda for your information, which lists the Session Chairs.

Thank you again for your contribution to help advance research to develop safer therapies for people with pain. We look forward to receiving your material and seeing you in November!

Mary Ann Pelleymounter
Victoria Smith
Richard Hargreaves and Simon Tate
The Workshop Planning Committee (copied)

Hi Jen, I have inserted two comments in the treatment adherence 3.5 section. Apologies, I was unable to send email yesterday. Thanks, Nelson

@pfizer.com and @lilly.com and dsi.com and @its.jnj.com and @jnj.com

From: Gewandter, Jennifer [mailto:Jennifer_Gewandter@URMC.Rochester.edu]

Sent: Saturday, January 19, 2019 12:12 PM

To: Kerns, Robert <Robert.Kerns@va.gov>; 'Hewitt, David' <david.hewitt@syneoshealth.com>; Philip Conaghan <P.Conaghan@leeds.ac.uk>; Farrar, John <jfarrar@pennmedicine.upenn.edu>; Mark P Jensen <mjensen@uw.edu>; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz' <NKatz@analgesicsolutions.com>; Markman, John <John_Markman@URMC.Rochester.edu>; sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com; daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; pcowan@theacpa.org; mduffy@flexiontherapeutics.com; rredwards@partners.org; rfreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djuge@horizonpharma.com; ekopecky@collegiumpharma.com; McDermott, Mike <Michael_McDermott@URMC.Rochester.edu>; gri@egalet.com; Kushang Patel <kvpatel@uw.edu>; porterl@ninds.nih.gov; rrauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu; neil@lotuscr.com; skljarevski_vladimir@lilly.com; DUpmalis@its.jnj.com; trudy.vanhove@jazzpharma.com; Sessler, Nelson <Nelson.Sessler@pharma.com>; wasanad@upmc.edu; witterj@mail.nih.gov; scott_evans@gwu.edu; shay.bujanover@jazzpharma.com;

[\[REDACTED\]](#); [\[REDACTED\]](#)

Cc: Dworkin, Robert <Robert_Dworkin@URMC.Rochester.edu>; Dennis C. Turk <turkdc@uw.edu>
Subject: Re: [EXTERNAL] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials-
invitation for authorship - with attachement

EXTERNAL_EMAIL

Dear Colleagues,

Thank you to those of you who responded to the below email. If you haven't yet responded, this is a friendly reminder that I am hoping to hear from everyone by **Wed Jan 23rd**. Please note that if you do not respond, I cannot include you as an author on the manuscript.

Best,
Jen

~~~~~  
Jennifer Gewandter, PhD, MPH

Assistant Professor

Department of Anesthesiology

University of Rochester School of Medicine and Dentistry  
601 Elmwood Avenue, Box 604  
Rochester, NY 14642

Ph: 585 276-5661

**From:** Jennifer Gewandter <jennifer\_gewandter@urmc.rochester.edu>

**Date:** Friday, January 11, 2019 at 1:39 PM

**To:** Robert Kerns <Robert.Kerns@va.gov>, "Hewitt, David" <david.hewitt@syneoshealth.com>, Philip Conaghan <P.Conaghan@leeds.ac.uk>, "Farrar, John" <jfarrar@pennmedicine.upenn.edu>, "mjensen@uw.edu" <mjensen@uw.edu>, "Eric.Devine@bmc.org" <Eric.Devine@bmc.org>, "a.kirkwood@ucl.ac.uk" <a.kirkwood@ucl.ac.uk>, "bernard.vrijens@mwv.com" <bernard.vrijens@mwv.com>, Nathaniel Katz <NKatz@analgesicsolutions.com>, John Markman <John\_Markman@URMC.Rochester.edu>, [REDACTED] [REDACTED], [REDACTED] [REDACTED], "sbujanover@depomed.com" <sbujanover@depomed.com>, Laurie Burke <lburke@loragroup.com>, "jcampbell@centrexion.com" <jcampbell@centrexion.com>, "daniel.carr@tufts.edu" <daniel.carr@tufts.edu>, "crystal.chen@biogen.com" <crystal.chen@biogen.com>, "raymond.y.cheung@pfizer.com" <raymond.y.cheung@pfizer.com>, Penney Cowan <pcowan@theacpa.org>, "mdoyle@flexiontherapeutics.com" <mdoyle@flexiontherapeutics.com>, Robert Edwards <RREDWARDS@PARTNERS.ORG>, rfreeman <rfreeman@bidmc.harvard.edu>, Ian Gilron <gilroni@queensu.ca>, "djacobs@dsi.com" <djacobs@dsi.com>, "djuge@horizonpharma.com" <djuge@horizonpharma.com>, "ekopecy@collegiumpharma.com" <ekopecy@collegiumpharma.com>, "McDermott, Mike"



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**Cc:** "Dworkin, Robert" <Robert\_Dworkin@URMC.Rochester.edu>, Dennis Turk <turkdc@uw.edu>  
**Subject:** RE: [EXTERNAL] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials- invitation for authorship - with attachement

Dear Colleagues,

Thanks very much for your input thus far on our data quality IMMPACT manuscript. I have attached a revised version with changes highlighted in red. Note, that I have not highlighted wording changes that did not changed the meaning. Please review the revised text and make any further suggestions related to that text.

Also, I have added all of the disclosures that I received. If you do not see yours there and would like to disclose something, please send it to me. Please also check your affiliation to make sure that I have accurately made modifications.

Considering the number of modifications to the paper is relatively small and [REDACTED] [REDACTED] I would greatly appreciate if you could send me your feedback by **Wednesday January 23<sup>rd</sup>**. If you have no further comments, please send me an email indicating that the current version is acceptable. **I need to hear from you in order to include you as an author.**

Best,  
Jen

~~~~~  
Jennifer Gewandter, PhD, MPH
Assistant Professor
Department of Anesthesiology and Perioperative Medicine
University of Rochester School of Medicine and Dentistry
601 Elmwood Avenue, Box 604
Rochester, NY 14642
Ph: 585 276-5661

From: Gewandter, Jennifer

Sent: Wednesday, January 2, 2019 12:13 PM

To: 'Kerns, Robert' <Robert.Kerns@va.gov>; 'Hewitt, David' <david.hewitt@syneoshealth.com>; Philip Conaghan <P.Conaghan@leeds.ac.uk>; Farrar, John <jfarrar@pennmedicine.upenn.edu>; Mark P Jensen <mjensen@uw.edu>; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz' <NKatz@analgesicsolutions.com>; Markman, John <John_Markman@URMC.Rochester.edu> [REDACTED]; [REDACTED]

sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com;
daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com;
pcowan@theacpa.org; mduoye@flexiontherapeutics.com; rredwards@partners.org;
rffreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djuge@horizonpharma.com;
ekopecy@collegiumpharma.com; McDermott, Mike <Michael_McDermott@URMC.Rochester.edu>;
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rtauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu; [REDACTED]
neil@lotuscr.com; skljarevski_vladimir@lilly.com; [REDACTED] <DUpmalis@its.inj.com>;
trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu;
witterj@mail.nih.gov; scott_evans@gwu.edu

Cc: Dworkin, Robert <Robert_Dworkin@URMC.Rochester.edu>; Dennis C. Turk <turkdc@uw.edu>

Subject: RE: [EXTERNAL] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials-
invitation for authorship - with attachement

Hi All,

Thanks very much for your input on our manuscript. I have gotten quite a few questions on the issues of how to disclose conflicts. Here is Bob's as an example of what we are looking for.

Robert H. Dworkin, PhD, has received in the past 36 months research grants and contracts from US Food and Drug Administration and US National Institutes of Health, and compensation for consulting on clinical trial methods from [REDACTED] Private Source

Private Source

Thanks

Jen

Jennifer Gewandter, PhD, MPH
Assistant Professor
Department of Anesthesiology and Perioperative Medicine
University of Rochester School of Medicine and Dentistry
601 Elmwood Avenue, Box 604
Rochester, NY 14642
Ph: 585 276-5661

From: Kerns, Robert <Robert.Kerns@va.gov>

Sent: Wednesday, January 2, 2019 11:18 AM

To: 'Hewitt, David' <david.hewitt@syneoshealth.com>; Philip Conaghan <P.Conaghan@leeds.ac.uk>;
Farrar, John <jfarrar@pennmedicine.upenn.edu>; Mark P Jensen <mjensen@uw.edu>; Gewandter,
Jennifer <Jennifer_Gewandter@URMC.Rochester.edu>; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk;
bernard.vrijens@mww.com; 'Nathaniel Katz' <NKatz@analgesicsolutions.com>; Markman, John
<John_Markman@URMC.Rochester.edu>; [REDACTED]; [REDACTED]
sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com;
daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com;

pcowan@theacpa.org; mdoyle@flexiontherapeutics.com; rredwards@partners.org;
rfreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djuge@horizonpharma.com;
ekopecy@collegiumpharma.com; McDermott, Mike <Michael_McDermott@URMC.Rochester.edu>;
[REDACTED]; gni@egalet.com; Kushang Patel <kvpatel@uw.edu>; porterl@ninds.nih.gov;
rrauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu; [REDACTED]
neil@lotuscr.com; skljarovski_vladimir@lilly.com; [REDACTED] DUpmalis@its.jnj.com;
trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu;
witterj@mail.nih.gov; scott_evans@gwu.edu
Cc: Dworkin, Robert <Robert_Dworkin@URMC.Rochester.edu>; Dennis C. Turk <turkdc@uw.edu>
Subject: RE: [EXTERNAL] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials-
invitation for authorship - with attachement

Thanks for including me.

Here is some additional feedback.

I don't think I have any conflicts, other than to disclose sources of funding for my research and honoraria from professional organizations for speaking and consultation. If a complete list of these sources is necessary, please let me know.

Bob

From: Hewitt, David [mailto:david.hewitt@syneoshealth.com]
Sent: Wednesday, January 02, 2019 9:40 AM
To: Philip Conaghan <P.Conaghan@leeds.ac.uk>; Farrar, John <jfarrar@pennmedicine.upenn.edu>; Mark P Jensen <mjensen@uw.edu>; Gewandter, Jennifer <Jennifer_Gewandter@URMC.Rochester.edu>; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz' <NKatz@analgesicsolutions.com>; Markman, John <John_Markman@URMC.Rochester.edu> [REDACTED] [REDACTED]; sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com; daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; pcowan@theacpa.org; mdoyle@flexiontherapeutics.com; rredwards@partners.org; rfreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djuge@horizonpharma.com; Kerns, Robert <Robert.Kerns@va.gov>; ekopecy@collegiumpharma.com; McDermott, Mike <Michael_McDermott@URMC.Rochester.edu>; [REDACTED] gni@egalet.com; Kushang Patel <kvpatel@uw.edu>; porterl@ninds.nih.gov; rrauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu [REDACTED] neil@lotuscr.com; skljarovski_vladimir@lilly.com; [REDACTED] DUpmalis@its.jnj.com; trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu; witterj@mail.nih.gov; scott_evans@gwu.edu
Cc: Dworkin, Robert <Robert_Dworkin@URMC.Rochester.edu>; Dennis C. Turk <turkdc@uw.edu>
Subject: RE: [EXTERNAL] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials-
invitation for authorship - with attachement

Please see some addition comments for consideration.

Regards,

David

David Hewitt, M.D.

*Chief Medical Officer, Medical Management and Scientific Services
Clinical Solutions*

Syneos Health

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From: Philip Conaghan [<mailto:P.Conaghan@leeds.ac.uk>]

Sent: Tuesday, January 01, 2019 8:07 AM

To: Farrar, John; Mark P Jensen; Gewandter, Jennifer; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz'; Markman, John; Hewitt, David; [REDACTED]

[REDACTED] sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com; daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; pcowan@theacpa.org; mduoye@flexiontherapeutics.com; redwards@partners.org; rffreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djuce@horizonpharma.com; robert.kerns@med.va.gov; ekopeccky@collegiumpharma.com; McDermott, Mike; [REDACTED] gni@egalet.com; Kushang Patel; porterl@ninds.nih.gov; rtauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu;

[REDACTED] neil@lotuscr.com; skljarevski_vladimir@lilly.com; [REDACTED]; DUpmalis@its.inj.com; trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu; witterj@mail.nih.gov; scott.evans@gwu.edu

Cc: Dworkin, Robert; Dennis C. Turk

Subject: [EXTERNAL] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials- invitation for authorship - with attachment

Dear Jen

Thanks for including me and thank you for this great draft, I have only added a couple of comments to the current version – see also my comment on pg 17 about mentioning QMS given increasing electronically-managed studies

Happy New Year all!

Philip

Philip Conaghan MBBS PhD FRACP FRCP

Professor of Musculoskeletal Medicine

Director, Leeds Institute of Rheumatic and Musculoskeletal Medicine,

University of Leeds

Deputy Director, NIHR Leeds Biomedical Research Centre,
Leeds Teaching Hospitals NHS Trust

From: Farrar, John <jfarrar@pennmedicine.upenn.edu>

Sent: 31 December 2018 17:37

To: Mark P Jensen <mjensen@uw.edu>; Gewandter, Jennifer

<Jennifer_Gewandter@URMC.Rochester.edu>; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk;
bernard.vrijens@mwv.com; 'Nathaniel Katz' <NKatz@analgesicsolutions.com>; Markman, John

<John_Markman@URMC.Rochester.edu>; David.Hewitt@inventivhealth.com; [Pii]
[Pii] sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com;

daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; Philip Conaghan
<P.Conaghan@leeds.ac.uk>; pcowan@theacpa.org; mdoyle@flexiontherapeutics.com;
rredwards@partners.org; rfreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com;
djuge@horizonpharma.com; robert.kerns@med.va.gov; ekopecky@collegiumpharma.com; McDermott,
Mike <Michael_McDermott@URMC.Rochester.edu>; [Pii]; gni@egalet.com;
Kushang Patel <kvpatel@uw.edu>; porterl@ninds.nih.gov; rrauck@ccrpain.com; a.rice@ic.ac.uk;
michael.rowbotham@ucsf.edu [Pii] neil@lotuscr.com; skljurevski_vladimir@lilly.com;

[Pii] DUpmalis@its.jnj.com; trudy.vanhove@jazzpharma.com;
nelson.sessler@pharma.com; wasanad@upmc.edu; witterj@mail.nih.gov; scott_evans@gwu.edu

Cc: Dworkin, Robert <Robert_Dworkin@URMC.Rochester.edu>; Dennis C. Turk <turkdc@uw.edu>

Subject: Re: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials- invitation for
authorship - with attachment

Sorry for not including. Here is the Attachment - Happy New Year. John

John T. Farrar, MD, PhD

Associate Professor of Epidemiology, Neurology, and Anesthesia

Center for Clinical Epidemiology and Biostatistics

University of Pennsylvania

Room 816 Blockley Hall

Phone: 215-898-5802

NOTE - NEW E-MAIL:

jfarrar@pennmedicine.upenn.edu

From: Farrar, John

Sent: Sunday, December 30, 2018 4:53 PM

To: Mark P Jensen; Gewandter, Jennifer; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz'; Markman, John; David.Hewitt@inventivhealth.com; [PII]; [PII] sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com; daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; p.conaghan@leeds.ac.uk; pcowan@theacpa.org; mduoye@flexiontherapeutics.com; redwards@partners.org; Farrar, John T.; rffreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djuge@horizonpharma.com; robert.kerns@med.va.gov; ekopeccky@collegiumpharma.com; McDermott, Mike; [PII]; gmi@egalet.com; Kushang Patel; porterl@ninds.nih.gov; rrauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu; [PII] neil@lotuscr.com; skljarevski_vladimir@lilly.com; [PII]; DUpmalis@its.jnj.com; trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu; witterj@mail.nih.gov; scott_evans@gwu.edu

Cc: Dworkin, Robert; Dennis C. Turk

Subject: Re: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials- invitation for authorship

Nice paper - A few additional small changes on top of Mark's. Happy new Year. John

John T. Farrar, MD, PhD

Associate Professor of Epidemiology, Neurology, and Anesthesia

Center for Clinical Epidemiology and Biostatistics

University of Pennsylvania

Room 816 Blockley Hall

Phone: 215-898-5802

NOTE - NEW E-MAIL:

jfarrar@pennmedicine.upenn.edu

From: Mark P Jensen <mjensen@uw.edu>

Sent: Wednesday, December 26, 2018 1:39 PM

To: Gewandter, Jennifer; Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz'; Markman, John; David.Hewitt@inventivhealth.com; [PII]

[Pii]; sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com; daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; p.conaghan@leeds.ac.uk; pcowan@theacpa.org; mdoyle@flexiontherapeutics.com; rredwards@partners.org; Farrar, John T.; rfreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djudge@horizonpharma.com; robert.kerns@med.va.gov; ekopecky@collegiumpharma.com; McDermott, Mike; [Pii] gni@egalet.com; Kushang Patel; porterl@ninds.nih.gov; rrauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu [Pii] neil@lotuscr.com; skljarovski vladimir@lilly.com; [Pii]; DUpmalis@its.jnj.com; trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu; witterj@mail.nih.gov; scott_evans@gwu.edu

Cc: Dworkin, Robert; Dennis C. Turk

Subject: [External] RE: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials- invitation for authorship

Greetings Jen et al.,

Nice summary! Please see attached for a number of minor suggested edits and couple of comments.

Cheers,
Mark

From: Gewandter, Jennifer <Jennifer_Gewandter@URMC.Rochester.edu>

Sent: Wednesday, December 12, 2018 6:48 AM

To: Eric.Devine@bmc.org; a.kirkwood@ucl.ac.uk; bernard.vrijens@mwv.com; 'Nathaniel Katz' <NKatz@analgesicsolutions.com>; Markman, John <John_Markman@URMC.Rochester.edu>; David.Hewitt@inventivhealth.com; Mark P Jensen <mjensen@uw.edu>; [Pii]

[Pii] sbujanover@depomed.com; lburke@loragroup.com; jcampbell@centrexion.com; daniel.carr@tufts.edu; crystal.chen@biogen.com; raymond.y.cheung@pfizer.com; p.conaghan@leeds.ac.uk; pcowan@theacpa.org; mdoyle@flexiontherapeutics.com; rredwards@partners.org; jfarrar@mail.med.upenn.edu; rfreeman@bidmc.harvard.edu; gilroni@queensu.ca; djacobs@dsi.com; djudge@horizonpharma.com; robert.kerns@med.va.gov; ekopecky@collegiumpharma.com; McDermott, Mike <Michael_McDermott@URMC.Rochester.edu>; [Pii] gni@egalet.com; Kushang Patel <kvpatel@uw.edu>; porterl@ninds.nih.gov; rrauck@ccrpain.com; a.rice@ic.ac.uk; michael.rowbotham@ucsf.edu [Pii] neil@lotuscr.com; skljarovski vladimir@lilly.com [Pii] DUpmalis@its.jnj.com; trudy.vanhove@jazzpharma.com; nelson.sessler@pharma.com; wasanad@upmc.edu; witterj@mail.nih.gov; scott_evans@gwu.edu

Cc: Dworkin, Robert <Robert_Dworkin@URMC.Rochester.edu>; Dennis C. Turk <turkdc@uw.edu>

Subject: IMMPACT meeting paper on Ensuring Data Quality in Clinical Trials- invitation for authorship

Dear Colleagues,

I am writing to invite you to provide feedback on the paper for the IMMPACT meeting on Ensuring Data Quality in Clinical Trials in which you participated in 2015. We thank you for your participation in the meeting and hope that you will want to contribute to this manuscript and be included as an author.

I have attached a first draft of the manuscript for your review.

Please pay careful attention to the following:

- (1) check your **name and affiliation** and make sure that everything is correct
- (2) provide your **complete list of conflicts of interest**. Please note that we have changed our policy to listing all conflicts rather than only those that you think are related to the work.

Please send me your feedback **by Friday January 4, 2019**.

At that time, I will incorporate any suggestions that I have received (highlighting changes in red text) and redistribute the manuscript for a final opportunity for feedback on the red text only.

If you do not wish to be an author on this paper please let me know so that I don't send you annoying reminder emails!

Best,
Jen

~~~~~  
Jennifer Gewandter, PhD, MPH  
Assistant Professor  
Department of Anesthesiology  
University of Rochester School of Medicine and Dentistry  
601 Elmwood Avenue, Box 604  
Rochester, NY 14642  
Ph: 585 276-5661

Not sure how I left you off this – sorry!!!

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Monday, July 29, 2019 9:25 AM  
**To:** Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; jdunlop@amgen.com; cflores2@its.nj.com; joffes@upenn.edu; Koroshetz, Walter (NIH/NINDS) [E] <koroshetzw@ninds.nih.gov>; mintun@avidrp.com; rmoscicki@phrma.org; j-paice@northwestern.edu; Rasmussen, Kurt (NIH/NIDA) [E] <kurt.rasmussen@nih.gov>; cstucky@mcw.edu; cveasley@cpralliance.org; kenneth.m.verburg@pfizer.com; AWittorf@AdvaMed.org; clifford.woolf@childrens.harvard.edu; Baker, Rebecca (NIH/OD) [E] <rebecca.baker@nih.gov>; Mellon, Dan (FDA/CDER) <Dan.Mellon@fda.hhs.gov>; dthomas@bio.org; Marler, John (FDA/CDRH) <john.marler@fda.hhs.gov>  
**Cc:** Colvis, Christine (NIH/NCATS) [E] <Christine.Colvis@nih.gov>; Oshinsky, Michael (NIH/NINDS) [E] <michael.oshinsky@nih.gov>; Pellemounter, Mary (NIH/NINDS) [E] <mary.pellemounter@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Cush, Stephanie (FNIH) [T] <scush@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Karp, Barbara (NIH/NINDS) [E] <KarpB@ninds.nih.gov>; Wright, Clinton (NIH/NINDS) [E] <clinton.wright@nih.gov>; Iyengar, Smriti (NIH/NINDS) [E] <smriti.iyengar@nih.gov>; Tamiz, Amir (NIH/NINDS) [E] <amir.tamiz@nih.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; jmayne@phrma.org; dfriend@bio.org; McManus, Ayanna (NIH/OD) [E] <Ayanna.McManus@nih.gov>; Finnegan, Sean (NIH/NCATS) [E] <sean.finnegan@nih.gov>; Jonson, Samantha (NIH/NCATS) [E] <samantha.jonson@nih.gov>; Walker, Paula (NIH/NINDS) [E] <walkerp@ninds.nih.gov>; NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>  
**Subject:** Agenda and COI Materials for Thursday 8-1-2019 Meeting of the HEAL Partnership Committee

Dear HEAL Partnership Committee,

Please find attached an agenda for Thursday's meeting of the HEAL Partnership Committee. We will gather in the Bethesda Marriott for our second in-person meeting.

As a reminder, all working group members must complete the attached Conflict of Interest form for **\*\*each\*\*** meeting – please submit your completed form to me directly. And as always, please feel free to reach out with any questions or concerns.

Looking forward to our discussion Thursday.

Warm regards,  
Rebecca

Rebecca G. Baker, Ph.D.  
Director, Helping to End Addiction Long-term (HEAL) Initiative  
Immediate Office of the Director  
National Institutes of Health  
Phone: 301 402 1994  
Email: [rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)

Dear HEAL Partnership Committee,

Many thanks to those who contributed to our April 15 meeting of the HPC and who sent along ideas for topics of interest. Notes from the meeting are attached.

The NINDS EPPIC team is still finalizing the anticipated launch date, and will keep this group up to date on progress.

For those who have not yet responded with suggestions for our next meeting, we discussed the following three possibilities:

- (1) preclinical screening and innovative technology,
- (2) animal models and associated preclinical testing, and
- (3) biomarkers and endpoints – would benefit from pending information about relevant grants to be awarded through HEAL.

If you have not already, please respond with your interest for upcoming topics, and your preference for whether the meeting should be virtual or face-to-face.

Thank you,

Rebecca

Attachment



## Helping to End Addiction Long-term (HEAL) Initiative HEAL Partnership Committee – Meeting II

April 15, 2019, 2:00–3:30 pm ET – Teleconference

### Attendees

Chris Austin, National Center for Advancing Translational Science (NCATS); Rebecca Baker, National Institutes of Health/Office of the Director, (NIH/OD); Christine Colvis, NCATS; Stephanie Cush, Foundation for the National Institutes of Health (FNIH); Chris Flores, Johnson and Johnson (J&J); Danielle Friend, Biotechnology Innovation Organization (BIO); Steven Joffe, University of Pennsylvania (UPenn); Samantha Jonson, NCATS; Barbara Karp, National Institute of Neurological Disorders and Stroke (NINDS); Walter Koroshetz, NINDS; Joseph Menetski, FNIH; Mark Mintun, Lilly; Emily Morgan, FNIH; Richard Moscicki, Pharmaceutical Research and Manufacturers of America, (PhRMA); Judith Paice, Northwestern University; Linda Porter, NINDS; Kurt Rasmussen, National Institute on Drug Abuse (NIDA); Bill Schmidt, FNIH; Erin Spaniol, NIH/OD; Amir Tamiz, NINDS; David Wholley, FNIH; Ashley Wittorf, AdvaMed; Clifford Woolf, Harvard; Clinton Wright, NINDS

### Agenda

1. Welcome and Review of Agenda
2. Review of Revised Asset Template and Information Dossier for EPPIC-Net
3. Communications Plan for the Request and Solicitation Process for EPPIC-Net
4. Scope and Potential Agenda Items for Next Meeting
5. Next Steps and Closing

### Action Items

| Action Item Description                                                                                                | Owner                                               |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| All HPC members must complete a conflict of interest form and return it to Rebecca Baker for each HPC meeting          | Rebecca Baker<br>NIH/OD                             |
| The Conflict of Interest and Confidentiality for Working Group Participants forms will be recirculated to HPC members. | Rebecca Baker<br>NIH/OD                             |
| Update the asset-entry template based on the feedback received during this teleconference.                             | Amir Tamiz<br>NINDS                                 |
| Update the asset dossier based on the feedback received during this teleconference.                                    | Amir Tamiz<br>NINDS                                 |
| Circulate an updated flow chart to HPC members outlining the process for asset submission to EPPIC-Net.                | Rebecca Baker<br>NIH/OD<br>&<br>Amir Tamiz<br>NINDS |

|                                                                                                                                                  |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Set a date to begin the solicitation process for EPPIC-Net and communicate timelines to the HPC, so they can communicate with their stakeholders | Rebecca Baker<br>NIH/OD |
| Solicit feedback from HPC members on the next topic to address with the HPC and timing of next meeting                                           | Rebecca Baker<br>NIH/OD |

## Meeting Minutes

### 1. Welcome and Review of Agenda

*Rebecca Baker, Director, HEAL Initiative, NIH/OD*

The HEAL Partnership Committee (HPC) is a subgroup within the larger HEAL Multi-Disciplinary Working Group (MDWG), which is tied to the NIH advisory councils. Therefore, this teleconference was publicly accessible via a listen-only line, and this summary will be available online. HPC members must provide Dr. Baker with a completed conflict of interest form for every meeting. As a courtesy, Dr. Baker will recirculate the Conflict of Interest and Confidentiality Information for Working Group Participants forms to all HPC members. The HPC was formed to provide expertise to the MDWG regarding HEAL research activities aimed at developing and testing new treatments (i.e., medications and devices, referred to here as “assets”) for pain and addiction via the Early Phase Pain Investigation Clinical-Network (EPPIC-Net).

Participants at the HPC face-to-face meeting in March began to determine the information that will be needed in order for the NIH to evaluate assets, including by providing feedback for the asset-entry templates and the more comprehensive asset dossiers, which have since been updated and circulated for HPC review. Additionally, participants at the March meeting specified the information that partners would need to disseminate to stakeholders. This discussion culminated in a draft EPPIC-Net handout, which was also circulated to participants for review.

### 2. Review of Revised Asset Template and Information Dossier for EPPIC-Net

*Amir Tamiz, NINDS; Clinton Wright, NINDS*

EPPIC-Net is a clinical trials network designed as a hub-and-spoke system. This means that the network consists of a clinical coordinating center and a data coordinating center which are each connected to numerous specialized clinical sites. These sites provide access to patients with specific conditions, creating a network to run early-phase exploratory trials investigating a broad spectrum of treatment modalities (i.e., drugs, biologics, devices, natural products, and surgical interventions) for acute and chronic pain. EPPIC-Net will also support biomarker validation, proof of mechanism, and deep phenotyping studies. A repository will contain all data generated by EPPIC-Net, as well as by select studies related to HEAL.

Assets will enter the network through a multistage review process. First, asset holders will complete a preliminary asset entry application template, providing limited information to facilitate initial asset review. If EPPIC-Net’s objective review panelists are interested in pursuing the asset, the asset holder will produce a detailed dossier with help from a contractor provided by EPPIC-Net. After a dossier is reviewed and approved by the objective review panel, EPPIC-Net will design a Phase 2 clinical trial to test the selected asset. Once approved, the protocol will enroll patients from EPPIC-Net sites.



### Template Feedback and Revisions

Participants at the March face-to-face meeting suggested making the template review process more feedback-oriented so that it is useful even for applicants whose assets are not yet ready for clinical trials. This would provide EPPIC-Net with a broader picture of the assets that are in development while helping holders of less mature assets. Participants also discussed incorporating the FDA Target Product Profile (TPP) into the dossier and advocated more robust collaboration with the FDA when preparing for clinical trials. The latest versions of both the template and the dossier incorporate recommendations from these discussions. The template is currently in version 9. The template draft was presented as an Excel sheet that will be integrated into a drop-down menu web form. The application template is two pages and should take asset owners approximately 1 to 2 hours to complete.

Since the March meeting, the HPC has resolved issues related to asset ownership, target populations, and safety/liability, in addition to other concerns. The template now contains two additional asset ownership questions. Applicants will also have space to answer high-level questions about ownership, such as whether the application comes from industry or academia. Applicants will also report whether they have the authority to propose the application, and if they do not, they will provide evidence that the asset owner is aware of the application and that an agreement between the applicant and the asset owner is in place.

The template contains separate sections for devices and biologics. Since the March meeting, fields have been added to record site and population information for any previous clinical trials. A space was added for applicants to report safety and liability concerns.

Offering further feedback on the version 9 document, participants recommended better aligning the device section with FDA standards by adding line items for expected FDA device class, expected product code, and device classification name. Participants also recommended tying device type to the ISO 10993 form. Dr. Tamiz will update the template to reflect these suggestions.

### Dossier Feedback and Revisions

Application review will begin once a large enough batch of template applications have been received. Top applications will move forward to the dossier stage. The dossier will then provide the EPPIC-Net team with access to all the asset information that would be included in an IND or IDE. A completed dossier will be approximately 10 to 15 pages and will include any information from from preclinical safety studies, IND or IDE, investigator brochures, and additional pharmacology studies.

After review, the dossiers will be assigned to one of three categories: (1) those ready for efficacy trials, (2) those that are of interest but not ready for efficacy trials, and (3) those that will not advance. For assets in category (2), the team will communicate to the asset owner what steps are required to advance the asset. Participants suggested that all applicants receive some level of feedback regarding their dossiers. The HPC will need a clear outline of how these communications will occur so that everyone understands the process and so that applicants can facilitate advancement of their assets in EPPIC-Net.

The dossier was also updated following suggestions at the face-to-face meeting and subsequent feedback:

- **Section 3** of the dossier now contains shortened TPP documentation to better harmonize applications for assets at varying stages of development.
- **Section 4**, which focuses on preclinical data, now requests more details regarding efficacy studies (e.g., replication information). This will allow the review panel to provide feedback regarding additional studies that may be needed to confirm or support the indication or population before conducting a clinical trial.



- **Section 5** has added more information about safety and whether decisions of go/no go were based around safety. This is consistent with the updates made to the template document.
- **Section 7** allows the objective review panel to learn more about the non-scientific decisions that contributed to development and current status of an asset (e.g., reasons for discontinuation, plans beyond phase 2 trials, conflicts of interest).

Additional feedback was provided during this teleconference. The dossier will be updated to reflect the following points:

- **Section 2d** refers to pharmacokinetics and pharmacodynamics but specifies only pharmacokinetics. The reference to pharmacodynamics should be dropped.
- **Section 4** should include a question about pediatric preclinical data and about any known or expected gender-based differences.
- **Section 5** should specify the applicant's envisioned comparators for a randomized trial or historic control data for a non-randomized trial.
- **Section 5** should contain, under "safety," a question regarding dependence or addiction.

Participants also suggested reviewing the document for potential duplications; Dr. Tamiz noted that some duplications were intentionally included.

Participants commented that the "conflict of interest" field is too broadly framed. Dr. Tamiz presented a hypothetical situation in which an academic investigator submits an asset held by a company. In this situation, the dossier should include an agreement between the academic and the asset-holder confirming that the asset-holder is aware of the application and is prepared to provide materials as needed. HPC members noted that this should be explained more clearly in the dossier. Examples will be added to specify the information that is being requested.

#### Other Next Steps

An updated process flow chart capturing the process of asset application from template to clinical trial is needed. Dr. Baker has created multiple flow charts capturing various stages of this process. Drs. Tamiz and Baker will work together to provide a finalized flow chart to the HPC.

Once experience is gained throughout the EPPIC-Net process, a frequently asked questions (FAQ) page will be added to the website to further assist applicants. The HPC will be asked to provide feedback once the FAQs have been drafted.

### **3. Communications Plan for the Request and Solicitation Process for EPPIC-Net**

*Rebecca Baker, Director, HEAL Initiative, NIH/OD*

In response to previous HPC member suggestions to develop EPPIC-Net outreach materials, a communications document was drafted. The 2-page document incorporates feedback from the March face-to-face meeting as well as comments received afterward. The first page contains a description of EPPIC-Net and the network's priorities. The second page concisely describes the entire process, starting with template submission and culminating in a clinical trial.

Dr. Baker noted that EPPIC-Net will be open to assets from foreign-based companies, as pain management and addiction are global issues. This information could be added in the proposed outline or handled as part of ancillary materials.

Participants suggested providing a broader outline of the HEAL initiative as part of the outreach materials. Dr. Baker remains open to suggestions regarding what asset owners may be interested in knowing.



Participants requested additional information regarding the forthcoming EPPIC-Net requests for proposals (RFPs). Currently there are several RFPs to build the infrastructure for EPPIC-Net and a review section to evaluate the applications. EPPIC-Net has developed a non-grant/non-contract process to review assets and launch trials. This is a unique approach that will not require a full proposal. NIH hopes this approach will reduce the time between template submission and clinical trial execution.

#### Possible EPPIC-Net Dissemination Methods

EPPIC-Net should leverage multiple dissemination methods to increase awareness of EPPIC-Net. This will include EPPIC-Net presentations at large conferences that present opportunities for interaction with potential asset holders. One such opportunity is the June BIO Convention, which features a planned session about NIH being a catalyst for opioid crisis research. There will be four sessions focused on addiction and pain. It would be possible to mention EPPIC-Net and to distribute handouts or other additional information for those who are interested.

Dr. Baker asked that the partners on the HPC assist in outreach efforts to member organizations within industry groups to promote interest among companies who might otherwise be unaware of EPPIC-Net.

Ms. Wittorf noted also the possibility of gaining information through the trans-agency memorandum of understanding for the FDA, which held an [innovation challenge](#) that received more than 250 applications. Only 10 of these were granted, so the 240 others may be eligible and available to join EPPIC-Net. Applicant information may be obtainable through FDA. The FDA website might also be used to promote awareness of EPPIC-Net. Industry publications could also be leveraged.

The HPC may also promote awareness of EPPIC-Net by responding to press requests.

#### **4. Scope and Potential Agenda Items for Next Face-to-Face Meeting**

*Rebecca Baker, Director, HEAL Initiative, NIH/OD*

Looking beyond EPPIC-Net, the HPC should consider (1) its potential value for the wider HEAL Initiative and (2) potential ideas for research activities and translational models for testing pain treatment.

Dr. Austin presented a brief use case for his system which allows for the mechanistic investigation of novel compounds. Through HEAL, his team is developing novel human cell-based platforms using induced pluripotent stem cells (iPSCs) from pain patients and healthy controls and is developing 3D printed tissue models of various levels of nerve access that mediate pain and addiction. Dr. Austin's team is also interested in partnering with companies to continue development of deprioritized compounds.

Dr. Joffe suggested that the EPPIC-Net infrastructure might offer the ability to set the design standards for pain trials (e.g., by establishing endpoints and biological correlatives).

Participants recognized the potential for expansion into three key areas: (1) preclinical screening and innovative technology, (2) animal models and associated preclinical testing, and (3) biomarkers and endpoints. Participants agreed to wait to pursue these areas until several anticipated relevant grants are awarded.

Mr. Schmidt suggested that EPPIC-Net ensure some interaction with the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTION) public-private partnership. EPPIC-Net already includes some representatives from ACTION. NIH expects the first EPPIC-Net trials to begin in 2020 and hopes to begin the asset submission and review process as soon as possible, to allow for 6-8 months between the first template submission and initiation of the first resulting clinical trial. There is no set time for the availability of the template and other documentation. Dr. Baker noted that a date does need to be set. She

will speak with the communications offices to determine a date by which to begin the solicitation process.

## 5. Next Steps and Closing

*Rebecca Baker, Director, HEAL Initiative, NIH/OD*

Topics for the next meeting will be obtained via email.  
Participants are reminded to complete their conflict of interest forms.

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Saturday, April 13, 2019 9:16 AM  
**To:** Austin, Christopher (NIH/NCATS) [E] <[austinc@mail.nih.gov](mailto:austinc@mail.nih.gov)>; [jdunlop@amgen.com](mailto:jdunlop@amgen.com); [cflores2@its.inj.com](mailto:cflores2@its.inj.com); [joffes@upenn.edu](mailto:joffes@upenn.edu); Koroshetz, Walter (NIH/NINDS) [E] <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>; [mintun@avidrp.com](mailto:mintun@avidrp.com); [rmoscicki@phrma.org](mailto:rmoscicki@phrma.org); [j-paice@northwestern.edu](mailto:j-paice@northwestern.edu); Rasmussen, Kurt (NIH/NIDA) [E] <[kurt.rasmussen@nih.gov](mailto:kurt.rasmussen@nih.gov)>; [cstucky@mcw.edu](mailto:cstucky@mcw.edu); [cveasley@cpralliance.org](mailto:cveasley@cpralliance.org); [kenneth.m.verburg@pfizer.com](mailto:kenneth.m.verburg@pfizer.com); [AWittorf@AdvaMed.org](mailto:AWittorf@AdvaMed.org); [clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu); [dthomas@bio.org](mailto:dthomas@bio.org); Marler, John (FDA/CDRH) <[john.marler@fda.hhs.gov](mailto:john.marler@fda.hhs.gov)>  
**Cc:** Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>; [schmidtwk@sbcglobal.net](mailto:schmidtwk@sbcglobal.net); Cush, Stephanie (FNIH) [T] <[scush@fnih.org](mailto:scush@fnih.org)>; Morgan, Emily (FNIH) [T] <[emorgan@fnih.org](mailto:emorgan@fnih.org)>; [rebecca.lazeration@roseliassociates.com](mailto:rebecca.lazeration@roseliassociates.com); Tamiz, Amir (NIH/NINDS) [E] <[amir.tamiz@nih.gov](mailto:amir.tamiz@nih.gov)>; Karp, Barbara (NIH/NINDS) [E] <[KarpB@ninds.nih.gov](mailto:KarpB@ninds.nih.gov)>; Wright, Clinton (NIH/NINDS) [E] <[clinton.wright@nih.gov](mailto:clinton.wright@nih.gov)>; Colvis, Christine (NIH/NCATS) [E] <[Christine.Colvis@nih.gov](mailto:Christine.Colvis@nih.gov)>; Jonson, Samantha (NIH/NCATS) [E] <[samantha.jonson@nih.gov](mailto:samantha.jonson@nih.gov)>; Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>; Spaniol, Erin (NIH/OD) [E] <[Erin.Spaniol@nih.gov](mailto:Erin.Spaniol@nih.gov)>; Baker, Rebecca (NIH/OD) [E] <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>; Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Subject:** Materials: Monday 4-15 Meeting of the HEAL Partnership Committee

Good morning,

Attached you will find an agenda and materials for our meeting of the HEAL Partnership Committee on Monday, April 15, 2019.

Please look out for detailed instructions for joining the webex meeting from my colleagues at the Foundations for the NIH, to be sent under separate cover.

As a reminder, please return to me the completed conflict of interest form, and do not hesitate to reach out with any questions or concerns.

Looking forward to our discussion Monday,

Rebecca

Rebecca G. Baker, Ph.D.  
Director, Helping to End Addiction Long-term (HEAL) Initiative  
Immediate Office of the Director  
National Institutes of Health  
Phone: 301 402 1994  
Email: [rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)



This subject line says 1 pm but the invite and all other invites say 2 pm – perhaps they open the line at 1

Im not sure either of us can register as participants -- will see as we go

**From:** Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>

**Sent:** Monday, April 15, 2019 1:03 PM

**To:** Austin, Christopher (NIH/NCATS) [E] <[austinc@mail.nih.gov](mailto:austinc@mail.nih.gov)>; Baker, Rebecca (NIH/OD) [E] <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>; Bill Schmidt <[schmidtwk@sbcglobal.net](mailto:schmidtwk@sbcglobal.net)>; Cheryl Stucky <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>; Chris Flores <[cflores2@its.jnj.com](mailto:cflores2@its.jnj.com)>; Christin Veasley <[cveasley@cpralliance.org](mailto:cveasley@cpralliance.org)>; Cush, Stephanie (FNIH) [T] <[scush@fnih.org](mailto:scush@fnih.org)>; John Dunlop <[jdunlop@amgen.com](mailto:jdunlop@amgen.com)>; Judith Paice <[jpaice@northwestern.edu](mailto:jpaice@northwestern.edu)>; Ken Verberg <[kenneth.m.verburg@pfizer.com](mailto:kenneth.m.verburg@pfizer.com)>; Koroshetz, Walter (NIH/NINDS) [E] <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>; Mark Minton <[mintun@avidrp.com](mailto:mintun@avidrp.com)>; Marler, John (FDA/CDRH) <[john.marler@fda.hhs.gov](mailto:john.marler@fda.hhs.gov)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>; Morgan, Emily (FNIH) [T] <[emorgan@fnih.org](mailto:emorgan@fnih.org)>; Patrizia Cavazzoni <[patrizia.cavazzoni@fda.hhs.gov](mailto:patrizia.cavazzoni@fda.hhs.gov)>; Rasmussen, Kurt (NIH/NIDA) [E] <[kurt.rasmussen@nih.gov](mailto:kurt.rasmussen@nih.gov)>; Rich Moscicki <[rmoscicki@phrma.org](mailto:rmoscicki@phrma.org)>; Steven Joffe <[joffes@upenn.edu](mailto:joffes@upenn.edu)>; Tamiz, Amir (NIH/NINDS) [E] <[amir.tamiz@nih.gov](mailto:amir.tamiz@nih.gov)>; Thomas, Dave <[dthomas@bio.org](mailto:dthomas@bio.org)>; Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Wittorf, Ashley <[awittorf@advamed.org](mailto:awittorf@advamed.org)>; Woolf, Clifford <[clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu)>; Cavazzoni, Patrizia (FDA/CDER) <[Patrizia.Cavazzoni@fda.hhs.gov](mailto:Patrizia.Cavazzoni@fda.hhs.gov)>; Wright, Clinton (NIH/NINDS) [E] <[clinton.wright@nih.gov](mailto:clinton.wright@nih.gov)>; Karp, Barbara (NIH/NINDS) [E] <[karpb@ninds.nih.gov](mailto:karpb@ninds.nih.gov)>; Jonson, Samantha (NIH/NCATS) [E] <[samantha.jonson@nih.gov](mailto:samantha.jonson@nih.gov)>; Spaniol, Erin (NIH/OD) [E] <[erin.spaniol@nih.gov](mailto:erin.spaniol@nih.gov)>  
**Cc:** Branker, Barri <[Bbranker@phrma.org](mailto:Bbranker@phrma.org)>; Bruning, Lynn <[lynn.bruning@childrens.harvard.edu](mailto:lynn.bruning@childrens.harvard.edu)>; Charlier, Maria (NIH/NINDS) [C] <[maria.charlier@nih.gov](mailto:maria.charlier@nih.gov)>; DeMarco, Devota R (FDA/CDER) <[Devota.DeMarco@fda.hhs.gov](mailto:Devota.DeMarco@fda.hhs.gov)>; Henrique, Gleise <[gleiseh@amgen.com](mailto:gleiseh@amgen.com)>; Huisman, Sherryll <[sherryll.huisman@nm.org](mailto:sherryll.huisman@nm.org)>; Lagos, Enrique (NIH/NCATS) [E] <[enrique.lagos@nih.gov](mailto:enrique.lagos@nih.gov)>; Shaver, Karen (NIH/NCCIH) [C] <[karen.shaver@nih.gov](mailto:karen.shaver@nih.gov)>; Walker, Paula (NIH/NINDS) [E] <[walkerp@ninds.nih.gov](mailto:walkerp@ninds.nih.gov)>; Paice, Judith <[JPaice1@nm.org](mailto:JPaice1@nm.org)>; Meltzer, Abbey (FNIH) [T] <[ameltzer@fnih.org](mailto:ameltzer@fnih.org)>; Samuel Thomas <[Samuel.Thomas@roseliassociates.com](mailto:Samuel.Thomas@roseliassociates.com)>; Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>; Rebecca Lazeration <[Rebecca.Lazeration@roseliassociates.com](mailto:Rebecca.Lazeration@roseliassociates.com)>; Lucas Smalldon <[Lucas.Smalldon@roseliassociates.com](mailto:Lucas.Smalldon@roseliassociates.com)>; Colvis, Christine (NIH/NCATS) [E] <[christine.colvis@nih.gov](mailto:christine.colvis@nih.gov)>

**Subject:** Dial-in Information for HEAL HPC Teleconference at 1 p.m. Eastern time

Dear HPC Members,

Please use the below link to join the WebEx Event:

<https://nih.webex.com/nih/onstage/g.php?MTID=efff5b520a4d355c0c7ec47dae2baffda>

Today's HPC Teleconference may be accessed by clicking the above link and registering with your full name and email address. After registering you will be prompted to join the WebEx Event as a 'panelist', this designation allows you to actively participate in the call. Once you've launched the WebEx application and joined; you will be given a dial-in number, meeting number, and attendee ID. We ask that you enter your attendee ID when dialing-in as it is what identifies you by name and panelist.

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Please reach out to Emily Morgan ([emorgan@fnihi.org](mailto:emorgan@fnihi.org)) if you have any trouble logging into the WebEx Event.

Thank you,

**Cheryl Melencio**

Executive Assistant, Research Partnerships

**Foundation for the National Institutes of Health**

(301) 402-4970

[fnihi.org](http://fnihi.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2018, the FNIH earned another 4-star rating from Charity Navigator and was recognized as an organization that exceeds industry standards.*

-----Original Appointment-----

**From:** Melencio, Cheryl (FNIH) [T]

**Sent:** Wednesday, March 27, 2019 11:31 AM

**To:** Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Baker, Rebecca (NIH/OD) [E]; Bill Schmidt; Cheryl Stucky; Chris Flores; Christin Veasley; Cush, Stephanie (FNIH) [T]; John Dunlop; Judith Paice; Ken Verberg; Koroshetz, Walter (NIH/NINDS) [E]; Mark Minton; Marler, John (FDA/CDRH); Menetski, Joseph (FNIH) [T]; Morgan, Emily (FNIH) [T]; Patrizia Cavazzoni; Rasmussen, Kurt (NIH/NIDA) [E]; Rich Moscicki; Steven Joffe; Tamiz, Amir (NIH/NINDS) [E]; Thomas, Dave; Wholley, David (FNIH) [T]; Wittorf, Ashley; Woolf, Clifford; Cavazzoni, Patrizia (FDA/CDER); Wright, Clinton (NIH/NINDS) [E]; Karp, Barbara (NIH/NINDS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Spaniol, Erin (NIH/OD) [E]

**Cc:** Branker, Barri; Bruning, Lynn; Charlier, Maria (NIH/NINDS) [C]; DeMarco, Devota R (FDA/CDER); Henrique, Gleise; Huisman, Sherryl; Lagos, Enrique (NIH/NCATS) [E]; Shaver, Karen (NIH/NCCIH) [C]; Walker, Paula (NIH/NINDS) [E]; Paice, Judith; Meltzer, Abbey (FNIH) [T]; Samuel Thomas; Porter, Linda (NIH/NINDS) [E]; Rebecca Lazeration; Lucas Smalldon; Colvis, Christine (NIH/NCATS) [E]

**Subject:** HEAL HPC Teleconference

**When:** Monday, April 15, 2019 2:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** See Webex information below

Dear HPC Members,

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<https://nih.webex.com/nih/onstage/g.php?MTID=efff5b520a4d355c0c7ec47dae2baffda>

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Please reach out to Emily Morgan ([emorgan@fnihi.org](mailto:emorgan@fnihi.org)) if you have any trouble logging into the WebEx Event.

Thank you,

**Sent items: @jnj.com and Pfizer.com**

This subject line says 1 pm but the invite and all other invites say 2 pm – perhaps they open the line at 1

Im not sure either of us can register as participants -- will see as we go

**From:** Melencio, Cheryl (FNIH) [T] <[cmelencio@fnihi.org](mailto:cmelencio@fnihi.org)>

**Sent:** Monday, April 15, 2019 1:03 PM

**To:** Austin, Christopher (NIH/NCATS) [E] <[austinc@mail.nih.gov](mailto:austinc@mail.nih.gov)>; Baker, Rebecca (NIH/OD) [E] <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>; Bill Schmidt <[schmidt@sbcbglobal.net](mailto:schmidt@sbcbglobal.net)>; Cheryl Stucky <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>; Chris Flores <[cflores2@its.jnj.com](mailto:cflores2@its.jnj.com)>; Christin Veasley <[cveasley@cpralliance.org](mailto:cveasley@cpralliance.org)>; Cush, Stephanie (FNIH) [T] <[scush@fnihi.org](mailto:scush@fnihi.org)>; John Dunlop <[jdunlop@amgen.com](mailto:jdunlop@amgen.com)>; Judith Paice <[jpaice@northwestern.edu](mailto:jpaice@northwestern.edu)>; Ken Verberg <[kenneth.m.verburg@pfizer.com](mailto:kenneth.m.verburg@pfizer.com)>; Koroshetz, Walter (NIH/NINDS) [E] <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>; Mark Minton <[mintun@avidrp.com](mailto:mintun@avidrp.com)>; Marler, John (FDA/CDRH) <[john.marler@fda.hhs.gov](mailto:john.marler@fda.hhs.gov)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>; Morgan, Emily (FNIH) [T] <[emorgan@fnihi.org](mailto:emorgan@fnihi.org)>; Patrizia Cavazzoni <[patrizia.cavazzoni@fda.hhs.gov](mailto:patrizia.cavazzoni@fda.hhs.gov)>; Rasmussen, Kurt (NIH/NIDA) [E] <[kurt.rasmussen@nih.gov](mailto:kurt.rasmussen@nih.gov)>; Rich Moscicki <[rmoscicki@phrma.org](mailto:rmoscicki@phrma.org)>; Steven Joffe <[soffes@upenn.edu](mailto:soffes@upenn.edu)>; Tamiz, Amir (NIH/NINDS) [E] <[amir.tamiz@nih.gov](mailto:amir.tamiz@nih.gov)>; Thomas, Dave <[dthomas@bio.org](mailto:dthomas@bio.org)>; Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Wittorf, Ashley <[awittorf@advamed.org](mailto:awittorf@advamed.org)>; Woolf, Clifford <[clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu)>; Cavazzoni, Patrizia (FDA/CDER) <[Patrizia.Cavazzoni@fda.hhs.gov](mailto:Patrizia.Cavazzoni@fda.hhs.gov)>; Wright, Clinton (NIH/NINDS) [E] <[clinton.wright@nih.gov](mailto:clinton.wright@nih.gov)>; Karp, Barbara (NIH/NINDS) [E] <[karpb@ninds.nih.gov](mailto:karpb@ninds.nih.gov)>; Jonson, Samantha (NIH/NCATS) [E] <[samantha.jonson@nih.gov](mailto:samantha.jonson@nih.gov)>; Spaniol, Erin (NIH/OD) [E] <[erin.spaniol@nih.gov](mailto:erin.spaniol@nih.gov)>  
**Cc:** Branker, Barri <[Bbranker@phrma.org](mailto:Bbranker@phrma.org)>; Bruning, Lynn <[lynn.bruning@childrens.harvard.edu](mailto:lynn.bruning@childrens.harvard.edu)>; Charlier, Maria (NIH/NINDS) [C] <[maria.charlier@nih.gov](mailto:maria.charlier@nih.gov)>; DeMarco, Devota R (FDA/CDER) <[Devota.DeMarco@fda.hhs.gov](mailto:Devota.DeMarco@fda.hhs.gov)>; Henrique, Gleise <[gleiseh@amgen.com](mailto:gleiseh@amgen.com)>; Huisman, Sherryll <[sherryll.huisman@nm.org](mailto:sherryll.huisman@nm.org)>; Lagos, Enrique (NIH/NCATS) [E] <[enrique.lagos@nih.gov](mailto:enrique.lagos@nih.gov)>; Shaver, Karen (NIH/NCCIH) [C] <[karen.shaver@nih.gov](mailto:karen.shaver@nih.gov)>; Walker, Paula (NIH/NINDS) [E] <[walkerp@ninds.nih.gov](mailto:walkerp@ninds.nih.gov)>; Paice, Judith <[JPaice1@nm.org](mailto:JPaice1@nm.org)>; Meltzer, Abbey (FNIH) [T] <[ameltzer@fnihi.org](mailto:ameltzer@fnihi.org)>; Samuel Thomas <[Samuel.Thomas@roseliassociates.com](mailto:Samuel.Thomas@roseliassociates.com)>; Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>; Rebecca Lazeration <[Rebecca.Lazeration@roseliassociates.com](mailto:Rebecca.Lazeration@roseliassociates.com)>; Lucas Smalldon <[Lucas.Smalldon@roseliassociates.com](mailto:Lucas.Smalldon@roseliassociates.com)>; Colvis, Christine (NIH/NCATS) [E] <[christine.colvis@nih.gov](mailto:christine.colvis@nih.gov)>  
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**Cheryl Melencio**

Executive Assistant, Research Partnerships

**Foundation for the National Institutes of Health**

(301) 402-4970

[fnihi.org](http://fnihi.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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**Cc:** Branker, Barri; Bruning, Lynn; Charlier, Maria (NIH/NINDS) [C]; DeMarco, Devota R (FDA/CDER); Henrique, Gleise; Huisman, Sherryl; Lagos, Enrique (NIH/NCATS) [E]; Shaver, Karen (NIH/NCCIH) [C]; Walker, Paula (NIH/NINDS) [E]; Paice, Judith; Meltzer, Abbey (FNIH) [T]; Samuel Thomas; Porter, Linda (NIH/NINDS) [E]; Rebecca Lazeration; Lucas Smalldon; Colvis, Christine (NIH/NCATS) [E]

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Please reach out to Emily Morgan ([emorgan@fnih.org](mailto:emorgan@fnih.org)) if you have any trouble logging into the WebEx Event.

Thank you,

We certainly look forward to having you

**From:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>

**Sent:** Monday, February 04, 2019 7:07 PM

**To:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>

**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

Hang in there! I look forward to continuing to be included,

Warmly yours Linda!

Cheryl

Cheryl L. Stucky, Ph.D.

Marvin Wagner Endowed Professor

Dept. Cell Biology, Neurobiology and Anatomy

Director, Neuroscience Doctoral Program

Director, Pain Division, Neuroscience Research Center

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee, WI 53226

Tel: 414-955-8373

Fax: 414-456-6517

Email: [cstucky@mcw.edu](mailto:cstucky@mcw.edu)

<https://www.mcw.edu/departments/cell-biology-neurobiology-and-anatomy/faculty/cheryl-stucky-phd>

**From:** Porter, Linda (NIH/NINDS) [E] <porterl@ninds.nih.gov>

**Sent:** Monday, February 04, 2019 4:23 PM

**To:** Stucky, Cheryl <cstucky@mcw.edu>

**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

ATTENTION: This email originated from a sender outside of MCW. Use caution when clicking on links or opening attachments.

---

Cheryl

Too many things are happening to keep up. I am happy to hear that you enjoyed the animal models meeting.

Sorry I missed you there

**From:** Stucky, Cheryl <cstucky@mcw.edu>

**Sent:** Monday, February 04, 2019 2:22 PM

**To:** Porter, Linda (NIH/NINDS) [E] <porterl@ninds.nih.gov>

**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

Hi Linda

I did get it thank you. The only sad thing is that   at a Chronic pain meeting and unlikely to be able to attend...I will try to make the call if at all possible though. I hope that I can still be involved even if I have to miss this day.

I tremendously enjoyed Chairing a session at the Animal Models evaluation meeting in DC last week. That was really valuable and fun.

All best

Cheryl

Cheryl L. Stucky, Ph.D.

Marvin Wagner Endowed Professor

Dept. Cell Biology, Neurobiology and Anatomy

Director, Neuroscience Doctoral Program

Director, Pain Division, Neuroscience Research Center

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee, WI 53226

Tel: 414-955-8373

Fax: 414-456-6517

Email: [cstucky@mcw.edu](mailto:cstucky@mcw.edu)

<https://www.mcw.edu/departments/cell-biology-neurobiology-and-anatomy/faculty/cheryl-stucky-phd>

**From:** Porter, Linda (NIH/NINDS) [E] <porterl@ninds.nih.gov>

**Sent:** Thursday, January 31, 2019 2:28 PM

**To:** Stucky, Cheryl <cstucky@mcw.edu>

**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative



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---

Cheryl

There was an email that went out at noon today re: a meeting of that committee. You are on the email. It came from Cheryl Melencio  
Please let me know if you don't have it.

Linda

**From:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>  
**Sent:** Thursday, January 31, 2019 2:09 PM  
**To:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

Hi Linda

I had not heard anything further about this HEAL Partnership committee; I hope that I'm still included in the committee.

The critical evaluation of animal models meeting that Michael Oshinsky has run has been GREAT. I really have enjoyed it and its been very useful for the field.

All best

Cheryl

Cheryl L. Stucky, Ph.D.  
Marvin Wagner Endowed Professor  
Dept. Cell Biology, Neurobiology and Anatomy  
Director, Neuroscience Doctoral Program  
Director, Pain Division, Neuroscience Research Center  
Medical College of Wisconsin  
8701 Watertown Plank Road  
Milwaukee, WI 53226  
Tel: 414-955-8373  
Fax: 414-456-6517  
Email: [cstucky@mcw.edu](mailto:cstucky@mcw.edu)  
<https://www.mcw.edu/departments/cell-biology-neurobiology-and-anatomy/faculty/cheryl-stucky-phd>

**From:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Sent:** Tuesday, December 18, 2018 3:12 PM  
**To:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>  
**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

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we recognize it's a lot to ask – there is so much swirling around – but all good.

**From:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>  
**Sent:** Tuesday, December 18, 2018 3:53 PM  
**To:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

Thank you for the additional information Linda. I'm concerned about time and commitment...and getting in over my head. I appreciate the clarification,  
All my best  
Cheryl

Cheryl L. Stucky, Ph.D.  
Marvin Wagner Endowed Professor  
Dept. Cell Biology, Neurobiology and Anatomy  
Director, Neuroscience Doctoral Program  
Director, Pain Division, Neuroscience Research Center  
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8701 Watertown Plank Road  
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Fax: 414-456-6517  
Email: [cstucky@mcw.edu](mailto:cstucky@mcw.edu)  
<https://www.mcw.edu/departments/cell-biology-neurobiology-and-anatomy/faculty/cheryl-stucky-phd>

**From:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Sent:** Tuesday, December 18, 2018 2:25 PM  
**To:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>  
**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

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Cheryl  
The biggest chore for this group will be review on the assets that would come into the early phase trial through the partnerships and so knowledge of the basic science of pain targets, biomarker validation etc is why you were selected – and highly recommended . That is the heavy lift. The workgroups will have clinical trial specialists. They have tried to bring in experts on both ends of the span if you will but don't expect individuals to cover both ends.  
Linda

**From:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>  
**Sent:** Tuesday, December 18, 2018 2:38 PM  
**To:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

Hi Linda  
What I wanted to ask you is whether I'm really the right choice to serve on this endeavor since I haven't done any clinical trials work. I'm concerned that I'm way out of my comfort zone and also the time commitment.  
Thanks!  
Cheryl

Cheryl L. Stucky, Ph.D.  
Marvin Wagner Endowed Professor  
Dept. Cell Biology, Neurobiology and Anatomy

Director, Neuroscience Doctoral Program  
Director, Pain Division, Neuroscience Research Center  
Medical College of Wisconsin  
8701 Watertown Plank Road  
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Tel: 414-955-8373  
Fax: 414-456-6517  
Email: [cstucky@mcw.edu](mailto:cstucky@mcw.edu)  
<https://www.mcw.edu/departments/cell-biology-neurobiology-and-anatomy/faculty/cheryl-stucky-phd>

**From:** Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Sent:** Tuesday, December 18, 2018 11:06 AM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>; Ward, Jackie (NIH/OD) [E] <[jackie.ward@nih.gov](mailto:jackie.ward@nih.gov)>; [j-paice@northwestern.edu](mailto:j-paice@northwestern.edu); [carmeng@umich.edu](mailto:carmeng@umich.edu); [clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu); [joffes@upenn.edu](mailto:joffes@upenn.edu)  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E] <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>; Baker, Rebecca (NIH/OD) [E] <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>; Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>  
**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

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---

In 6 languages!!

**From:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Sent:** Tuesday, December 18, 2018 12:03 PM  
**To:** Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>; Ward, Jackie (NIH/OD) [E] <[jackie.ward@nih.gov](mailto:jackie.ward@nih.gov)>; [j-paice@northwestern.edu](mailto:j-paice@northwestern.edu); [carmeng@umich.edu](mailto:carmeng@umich.edu); [clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu); [joffes@upenn.edu](mailto:joffes@upenn.edu)  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E] <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>; Baker, Rebecca (NIH/OD) [E] <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>; Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>; Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
**Subject:** Re: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

I have the same problem

----- Original Message -----

From: "Stucky, Cheryl" <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>  
Date: Tue, Dec 18, 2018, 12:02 PM  
To: "Ward, Jackie (NIH/OD) [E]" <[jackie.ward@nih.gov](mailto:jackie.ward@nih.gov)>, "[j-paice@northwestern.edu](mailto:j-paice@northwestern.edu)" <[j-paice@northwestern.edu](mailto:j-paice@northwestern.edu)>, "[carmeng@umich.edu](mailto:carmeng@umich.edu)" <[carmeng@umich.edu](mailto:carmeng@umich.edu)>, "[clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu)" <[clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu)>, "[joffes@upenn.edu](mailto:joffes@upenn.edu)" <[joffes@upenn.edu](mailto:joffes@upenn.edu)>  
CC: "Koroshetz, Walter (NIH/NINDS) [E]" <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>, "Baker, Rebecca (NIH/OD) [E]" <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>, "Wholley, David (FNIH) [T]" <[dwholley@fnih.org](mailto:dwholley@fnih.org)>, "Melencio, Cheryl (FNIH) [T]" <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>, "Porter, Linda (NIH/NINDS) [E]" <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>  
Subject: RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative



Hi Jackie

The passcode given me  Passcode:   
Isn't working....says leader pass has already been entered

Thanks

Cheryl

Cheryl L. Stucky, Ph.D.

Marvin Wagner Endowed Professor

Dept. Cell Biology, Neurobiology and Anatomy

Director, Neuroscience Doctoral Program

Director, Pain Division, Neuroscience Research Center

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee, WI 53226

Tel: 414-955-8373

Fax: 414-456-6517

Email: [cstucky@mcw.edu](mailto:cstucky@mcw.edu)

<https://www.mcw.edu/departments/cell-biology-neurobiology-and-anatomy/faculty/cheryl-stucky-phd>

**From:** Ward, Jackie (NIH/OD) [E] <[jackie.ward@nih.gov](mailto:jackie.ward@nih.gov)>

**Sent:** Wednesday, December 12, 2018 9:41 AM

**To:** [j-paice@northwestern.edu](mailto:j-paice@northwestern.edu); [carmeng@umich.edu](mailto:carmeng@umich.edu); Stucky, Cheryl <[cstucky@mcw.edu](mailto:cstucky@mcw.edu)>;  
[clifford.woolf@childrens.harvard.edu](mailto:clifford.woolf@childrens.harvard.edu); [joffes@upenn.edu](mailto:joffes@upenn.edu)

**Cc:** Koroshetz, Walter (NIH/NINDS) [E] <[koroshetzw@ninds.nih.gov](mailto:koroshetzw@ninds.nih.gov)>; Baker, Rebecca (NIH/OD) [E] <[rebecca.baker@nih.gov](mailto:rebecca.baker@nih.gov)>; Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>; Porter, Linda (NIH/NINDS) [E] <[porterl@ninds.nih.gov](mailto:porterl@ninds.nih.gov)>

**Subject:** RE: Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

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Dear Drs. Paice, Green, Stucky, Woolf, and Joffe,

Walter's email about this committee may have been a bit out of the blue for you. Rebecca Baker and myself, along with our colleagues at the Foundation for NIH, would like give you some background on these efforts in order to set the stage for Wednesday's call (which we hope you'll be able to make!). We are aiming for a short call on Tuesday Dec. 18 at 12 pm EST. I will be sending an event invitation out shortly for that with a call-in number. Please let me know if you aren't able to make it.

All the best,

Jackie

Jacqueline Ward, PhD

AAAS Science & Technology Policy Fellow

Office of the Director, NINDS

**From:** Koroshetz, Walter (NIH/NINDS) [E] <koroshetzw@ninds.nih.gov>

**Sent:** Tuesday, December 11, 2018 9:27 PM

**To:** cflores2@its.jnj.com; kenneth.m.verburg@pfizer.com; mintun@avidrp.com; jdunlop@amgen.com; cveasley@cpralliance.org; rmoscicki@phrma.org; cesham@bio.org; afish@AdvaMed.org; joffes@upenn.edu;; j-paice@northwestern.edu; carmeng@umich.edu; cstucky@mcw.edu; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>

**Cc:** Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Austin, Christopher (NIH/NCATS) [E] <austinc@mail.nih.gov>; Volkow, Nora (NIH/NIDA) [E] <nvolkow@nida.nih.gov>; Pena, Carlos L (FDA/CDRH) <Carlos.Pena@fda.hhs.gov>; Baker, Rebecca (NIH/OD) [E] <rebecca.baker@nih.gov>; Stein, Jack (NIH/NIDA) [E] <jack.stein@nih.gov>; Rasmussen, Kurt (NIH/NIDA) [E] <kurt.rasmussen@nih.gov>; Ward, Jackie (NIH/OD) [E] <jackie.ward@nih.gov>; Walker, Paula (NIH/NINDS) [E] <walkerp@ninds.nih.gov>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; dfriend@bio.org; kshultz@advamed.org; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>

**Subject:** Invitation to participate in Dec. 19 planning call for the NIH HEAL Initiative

Dear colleagues,

As you may know, NIH has launched the NIH Helping End Addiction Long-term (HEAL) Initiative to provide scientific solutions to the opioid crisis. Just yesterday, NIH released 36 new funding opportunities as part of HEAL, including announcement of a new clinical trials network for the testing of early-phase pain interventions. These FOAs were informed by our engagement with stakeholders across disciplines and sectors, and we thank you for your contributions.

Our next step is to formalize a structure for the NIH HEAL Partnership with the goal of having our first official meeting in the new year. I'd like to convene an initial planning call for this group on Dec. 19 from 1-3 pm. Ms. Paula Walker will be following up shortly with an event invite and a telecon number. Please accept my apologies for the short notice.

If you are unable to join, we will be sending out a summary of the call and David Wholley has offered to follow up individually with those unable to attend.

For more information on the HEAL Initiative, please read our updated [research plan](#) and take a look at our [HEAL website](#).

Thank you and looking forward to our discussion,

Walter

Director, National Institute of Neurological Disorders and Stroke  
National Institutes of Health

@medtronics. Com

-----Original Appointment-----

**From:** Bent, Robyn (NIH/NIAMS) [E] <robyn.bent@nih.gov>

**Sent:** Wednesday, April 3, 2019 9:28 AM



**To:** Bent, Robyn (NIH/NIAMS) [E]; BACPAC; Peng, Grace (NIH/NIBIB) [E]; Wolfson, Michael (NIH/NIBIB) [E]; Chen, Wen (NIH/NCCIH) [E]; Eldadah, Basil (NIH/NIA) [E]; Marden, Sue (NIH/NICHD) [E]; Thomas, David (NIH/OD) [E]; Tully, Lois (NIH/NINR) [E]; Hailu, Benyam (NIH/NIMHD) [E]; Begg, Lisa (NIH/OD) [E]; Langhals, Nick (NIH/NINDS) [E]; Cernich, Alison (NIH/NICHD) [E]; Weber, Wendy (NIH/NCCIH) [E]; Oshinsky, Michael (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Pelleymounter, Mary (NIH/NINDS) [E]; Douthard, Regine (NIH/OD) [E]; NIAMS Conference Room Dem1/803; Carter, Robert (NIH/NIAMS) [E]; Serrate-Sztejn, Susana (NIH/NIAMS) [E]; Lester, Gayle (NIH/NIAMS) [E]; Witter, James (NIH/NIAMS) [E]; Washabaugh, Chuck (NIH/NIAMS) [E]; Zheng, Xincheng (NIH/NIAMS) [E]; Wang, Yan (NIH/NIAMS) [E]; Nelson, Melinda (NIH/NIAMS) [E]; [Jeremy.Brown@nih.gov](mailto:Jeremy.Brown@nih.gov)

**Subject:** NIH HEAL Initiative: Back Pain Consortium (BACPAC) Research Program

**When:** Wednesday, April 24, 2019 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** Democracy 1- Suite 800 or via WebEx

**UPDATED 23 April 2019 → Agenda, Award and Decision Process, List of Grants, Grant Abstracts Uploaded**

Dear All,

We have updated the meeting invite with the following documents. These are provided for your convenience but we understand that you may not have time to review them prior to the meeting. We will provide additional information and discussion on Wednesday.

1. Meeting agenda
2. Award/Decision Process Document
3. Spreadsheet of BACPAC Grants
4. U24 BACPAC Abstracts
5. U19 BACPAC Abstracts
6. UG3/UH3 BACPAC Abstracts
7. UH2/UH3 BACPAC Abstracts

Best regards,  
Robyn Bent

---

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## ABSTRACT TEMPLATE

**Tom Jones, M.D. [Presenter Name/Credentials: Arial 12 pt, Bold]**

**The genetics of bone strength in mice [Presentation Title: Arial 12 pt, Bold]**

Smith, S.<sup>2</sup>, Jones, T.<sup>1</sup>, **Wilson, A.<sup>2</sup>**, Williams, J.<sup>3</sup>, Brown, M.<sup>1,2,3,4</sup> [All authors/co-authors: Arial 11 pt, list in any order, bold primary author]

*<sup>1</sup>Department of Surgery, Medical College of Wisconsin, Milwaukee, WI; <sup>2</sup>Department of Physiology, Medical College of Wisconsin, Milwaukee, WI; <sup>3</sup>Department of Cell Biology, Neurobiology & Anatomy, Medical College of Wisconsin, Milwaukee, WI; <sup>1, 2, 3, 4</sup>Children's Hospital in Wisconsin, Milwaukee, WI*  
[Affiliations: Arial 10 pt, Italics]

[Arial 11 pt, 250 words or less, block format] The purpose of this study is to identify relationships between the physical and genetic characteristics of bones in mice. The physical characteristics include size, density, and the force required to break the bone, while the genetic ones are the genes of the marker loci associated with the genes that affect these qualities. This study uses strains of mice with reduced genetic variation. The two strains of mice that are the most phenotypically extreme, meaning those with the strongest and weakest bones, are crossed. The F2 generation from that cross is then analyzed. The results of this analysis can be used to find which genotypes correlate with specific bone properties like size, density, and failure load. The anticipated outcome of this lab is the identification of the genotypes that affect bone strength in mice. The findings may be useful in treating medical conditions that are related to bone strength.

## SPEAKER BIOGRAPHY TEMPLATE

**First and Last Name, Credentials [Arial 11 pt, Bold]**

Senior Investigator, Gladstone Institute of Cardiovascular Disease

Professor, Department of Medical Genetics

Professor, Department of Molecular Pharmacology

University of California, San Francisco, CA

[Titles and Affiliations: Arial 11 pt]

[Arial 11 pt, 250 words or less, block format] First and last name is an investigator at the Gladstone Institutes and a professor in the University of California, San Francisco (UCSF) Division of Genomic Medicine. Dr. XXX's research focuses on human genetics that lead to cardiovascular diseases, such as cardiac arrhythmias and cardiomyopathy. His major model system is induced pluripotent stem (iPS) cells that are engineered to test the role of specific genetic changes on disease. Dr. XXX began his research career by working for two years with XXX at the XXX. He then completed his residency at XXX and a postdoctoral fellowship in the laboratory of XXX at

UCSF. In 1995, Dr. XXX joined the Gladstone Institutes and the UCSF faculty, advancing to senior investigator at Gladstone and Professor at UCSF. He is also the Gladstone Scientific Officer for Technology and Innovation. Dr. XXX is the founder of several public stem cell and genomics projects including XXX, XXX, XXX, and XXX. He pioneered the field of XXX using XXX for XXX. He was the founding director of the Gladstone Genomics Core and the Gladstone Stem Cell Core. Dr. XXX leads the Gladstone Stem Cell Training Program, is the principal investigator on multiple research grants from the XXX, and serves on multiple advisory boards. He is a member of several honorary societies, including the XXX, and is a Fellow in the XXX.



# Discovery and Validation of Biomarkers to Develop Non-Addictive Therapeutics for Pain

*Marriott Wardman-Park*

*2660 Woodley Rd NW, Washington, DC 20008*

**November 14-15, 2018**

## **Introduction**

More than 25 million Americans suffer from daily chronic pain, a highly debilitating medical condition that is complex and difficult to manage. In recent decades, there has been an overreliance on the prescription of opioids for chronic pain, contributing to an epidemic of opioid overdose deaths and addictions. Innovative scientific solutions to develop alternative treatment options for pain management are thus needed. NIH recently released a research plan for a broad and aggressive effort to accelerate scientific solutions to address the opioid crisis. The [NIH HEAL \(Helping to End Addiction Long-Term\) Initiative](#) will advance research to develop safer therapies for people with pain through a multi-pronged approach.

The challenges facing the development of non-opioid alternative pain medications include: challenging and costly clinical design requirements, poor predictive power of preclinical models, and a paucity of validated targets. In addition, patient populations are heterogeneous across multiple pain conditions, with broad variability in individual responses to interventions. Another major barrier to advancing new pain treatments is the inability to measure objectively the biological effect of a treatment in these complex patients.

The NIH HEAL Initiative provides funds for research to discover and validate biomarkers for pain that can serve as such objective measures that will help define patient populations for clinical trials. The use of objective biomarkers and endpoints throughout the drug discovery and development process is critical, as it would help to define pathophysiologic subsets of pain, evaluate target engagement of new drugs, and predict analgesic efficacy of new drugs. Nevertheless, such biomarkers and endpoints remain limited and very few have been validated.

Therefore, the overarching purpose of this workshop is: 1) to inform the community about current regulatory standards and guidelines for the development of biomarkers and endpoints, 2) to evaluate the state of the science in pain biomarker development and 3) to explore potential scientific and collaborative approaches that could facilitate the discovery and

validation of robust biomarkers and endpoints that would provide the tools necessary for the diagnosis and treatment of pain conditions.

### **Workshop Goals**

- Inform the community about current regulatory standards and guidelines for the development of biomarkers and endpoints
- Explore the state-of-the-science of different types and modalities of biomarkers for chronic pain and identify the research needed to stimulate their development in a manner that will withstand rigorous validation
- Identify roadblocks and gaps in the development of strong candidate biomarkers and endpoints for chronic pain indications that will withstand rigorous validation
- Identify opportunities to address challenges and gaps
- Convene academic, biopharmaceutical industry, and government scientists working on biomarker identification and discovery to share and discuss progress, successes, challenges, gaps, and potential solutions going forward.

### **Workshop Deliverables**

- Recommendations/guidelines for best practices in biomarker discovery and validation
- Publication of a white paper summarizing workshop findings/guidelines

Formation of a core working group representing government, academia and industry that regularly convenes to evaluate progress and remaining challenges in the area of pain biomarker and endpoint development



**Helping to End Addiction Long-term (HEAL)**  
**HEAL Partnership Committee (HPC) – Meeting II (Teleconference)**

**Monday, April 15, 2019**

**2:00 PM – 3:30 PM ET**

*Please use the below link to join the WebEx Event:*

<https://nih.webex.com/nih/onstage/g.php?MTID=efff5b520a4d355c0c7ec47dae2baffda>

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>2:00PM-2:05PM</b> | <b>Roll Call</b><br><i>FNIH</i>                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>2:05PM-2:10PM</b> | <b>Welcome and Review of Agenda</b><br><i>Rebecca Baker, Director, HEAL Initiative, Office of the Director, National Institutes of Health</i>                                                                                                                                                                                                                                                                                     |
| <b>2:10PM-2:45PM</b> | <b>Review of Revised Asset Template and Information Dossier for EPPIC Net</b><br><i>Amir Tamiz, National Institute of Neurological Disorders and Stroke</i> <ul style="list-style-type: none"><li>- Are the proposed documents complete?</li><li>- Do they strike the right balance between comprehensiveness and ease of use?</li><li>- Are there any additional suggestions regarding the request and review process?</li></ul> |
| <b>2:45PM-3:10PM</b> | <b>Communications Plan for the Request and Solicitation Process for EPPIC Net</b><br><i>Rebecca Baker, NIH Office of the Director – Discussion Lead</i> <ul style="list-style-type: none"><li>- Audiences, key messages, desired medium</li><li>- Is the draft communication document appropriate? Changes?</li><li>- Plans for distributing this document and other communications efforts:</li></ul>                            |
| <b>3:10PM-3:25PM</b> | <b>Scope and Potential Agenda Items for Planned for Next Face to Face Meeting</b> <ul style="list-style-type: none"><li>- Priorities for discussion – <i>Rebecca Baker</i></li><li>- Discussion – <i>All</i></li></ul>                                                                                                                                                                                                            |
| <b>3:25PM-3:30PM</b> | <b>Next Steps and Closing</b><br><i>Rebecca Baker, NIH Office of the Director</i>                                                                                                                                                                                                                                                                                                                                                 |

**Pre-Read Materials:**

- *Agenda*
- *Conflict of Interest Disclosure*
- *Revised Asset Request Template and Dossier Forms*
- *Draft Communication Document*